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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,280	12/29/2000	D. Scott Wilbur	33700WC005	6495
441	7590	07/14/2005	EXAMINER	
SMITH, GAMBRELL & RUSSELL, LLP 1850 M STREET, N.W., SUITE 800 WASHINGTON, DC 20036			KANTAMneni, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 07/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/750,280	WILBUR ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shobha Kantamneni	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 April 2005.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33,34,36,38 and 40-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33, 34, 36, 38, 40, 41, 55-59, 62, 64-67, 70, 73-74, 88-89 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 33, 34, 36, 38, and 40-97 are pending. Claims 42-54, 60, 61, 63, 68, 69, 71, 72, 75-87 and 90-97 are withdrawn from consideration.

The Amendment received on 04/18/2005, wherein claim 70 has been amended to recite only reagent 45, and claim 98 has been cancelled.

Applicant's cancellation of claim 98, and amending claim 70 to recite only reagent 45 is sufficient to overcome the rejection of claims 70 and 98 under U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments have been considered but are not persuasive, and the rejection of claims 73-74 under 35 U.S.C. 112, first paragraph is MAINTAINED, because the specification, while being enabling for diagnosis of myocardial infarction and certain cancers and treatment of certain cancers, does not reasonably provide enablement for **diagnosis and treatment of any condition or disease in a mammal**.

Applicant's cancellation of claim 98 has overcome the rejection of claim 98 only under 35 U.S.C. 103(a) as being unpatentable over Wilber et al. (WO 97/29114) in view of Rosebrough, The Journal of Pharmacology and Experimental Therapeutics, vol. 265, No.1, 1993, 408-415.

Applicant's cancellation of claim 98 has overcome the rejection of claim 98 only under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 17-19, and 21-23 of copending Application No. 09/519998.

The rejection of claims 33, 34, 40, 41, 55-59, 62, 64-67, 70, 73-74, 88-89 under 35 U.S.C. 103(a) as being unpatentable over Wilber et al. (WO 97/29114) in view of Rosebrough, The Journal of Pharmacology and Experimental Therapeutics, vol. 265, No.1, 1993, 408-415 is MAINTAINED. For reasons see under Response to Applicant's Arguments/Amendment.

The rejection of claims 36, and 38 under 35 U.S.C. 103(a) as being unpatentable over Wilbur et al. and Rosebrough as applied to claims 33, 34, 40, 41, 55-59, 62, 64-67, 70, 73-74, 88-89, 98, and further in view of Griffiths (5,482,698) is MAINTAINED as discussed in the previous office action, and those under Response to Applicant's Arguments.

The rejection of claims 33, 34, 36, 38, 55-59, 62, 64-67, 70, 73-74, and 88-89 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 17-19, and 21-23 of copending Application No. 09/519,998 is MAINTAINED.

***Response to Applicant's Arguments/Amendment***

Applicant argues that "The paper by Rosenbrough (Journal of Pharmacology Experimental Therapeutics 265, 408-415, 1993) does not teach one skilled in the art that conjugation of biotin with cysteine will provide complete blockage of biotinamide cleavage by the enzyme biotinidase when that conjugate is coupled with another molecule." This argument is not persuasive because 1) applicant is arguing against individual reference when the rejection was based on combination of references, 2) Rosenbrough teaches that introduction of a carboxyl group alpha to the amide bond of

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biotinamide, blocks the biotinidase activity, thereby increasing the stability of biotinamide bond toward enzymatic cleavage. Thus, it would have been obvious to a person of ordinary skill in the art at the time of invention, to use an aspartyl moiety which contains a beta carboxylate group as discussed in the previous office action, dated 11/17/2004, with the expectation of stabilizing the biotinamide bond towards enzymatic cleavage.

Applicant argues that "While in the Rosebrough paper it is stated that the biotin-cysteine-deferoxamine derivative (DACB) maintained its ability to bind avidin in vitro and in vivo, the binding affinity relative to native biotin was not determined. Biotin derivatives that have low binding affinities maintain their ability to bind with avidin, but they are not useful in the intended biomedical application". This argument is not persuasive because the argument is not commensurate with the scope of the instant claims. The claims are directed to a single molecule reagent, and the intended use of the reagent is not given any patentable weight. It is also respectfully pointed out that the introduction of carboxyl group adjacent to the amide bond cleavage site of biotinamide maintained the ability of DACB to bind to avidin. Thus even though Rosenbrough does not exemplify the binding affinity relative to native biotin, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ, 570

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(CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983).

Applicant argues that "one of ordinary skill in the art would not necessarily have been expected the results obtained when using an alpha carboxylate to correlate to an aspartyl moiety". Applicants argument alone is not persuasive because of lack of support, unless data is provided to show that the alpha carboxylate is substantially different from aspartyl moiety which introduces a beta carboxylate group to the amide bond in linker 1, and provides unexpected property for this single molecule reagent. Note that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F. 3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). The burden is shifted to Applicant to show factually supported objective evidence to rebut the *prima facia* case of obviousness over prior art.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAOJIA A. JIANG, PH.D.  
PRIMARY EXAMINER

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